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**PLANT-INCORPORATED PROTECTANT RULES AFFIRMED BY ADMINISTRATION;
COMMENTS INVITED ON SUPPLEMENTAL NOTICE AND REPORT**

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EPA Administrator Christie Whitman has signed three final rules, published today in the Federal Register, that clarify and strengthen the framework for EPA to oversee “plant-incorporated protectants.” Plant-incorporated protectants are materials that enable a plant to protect itself from pests, such as insects, viruses and fungi, because the plant produces its own pesticide. Under the rules announced today, plant-incorporated protectants derived from biotechnology will be regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and under the Federal Food, Drug, and Cosmetic Act (FFDCA) to ensure protection of human health and the environment.

“Developing this framework means that EPA’s current system of rigorous scientific evaluation for plant-incorporated protectants will continue,” said Whitman. “There has been an open and transparent process of scientific consultation and public comment leading to the finalization of these rules. They reflect EPA’s commitment to sound science and an even-handed regulatory process.”

Today’s action finalizes several regulatory steps first proposed by EPA in 1994, and largely followed by the Agency since that time. In the intervening years, the Agency consulted with independent panels of scientists and solicited public comments on a variety of issues related to the rules. Whitman’s approval also follows a thorough review of the regulations by the Bush Administration to ensure that EPA’s actions continue to provide strong protections for public and environmental health in biotechnology issues. These rules had originally been approved in January by former EPA Administrator Carol Browner, but were subsequently withdrawn to provide the incoming Administration with an opportunity for their review.

The new rules ensure that genetically engineered plant-incorporated protectants will meet federal safety standards through as rigorous EPA evaluation as traditional pesticide registrations. If the Agency determines that plant-incorporated protectants (PIPs) pose little or no health or environmental risk, they will be exempted from certain regulatory requirements. For example, PIPs developed through conventional breeding will be exempt from requirements under FIFRA and FFDCA. However, manufacturers must still report any adverse effects, should any occur. The rules also exempt genetic material (i.e., DNA) that creates the pesticidal substance in the plant from maximum residue levels (called a “tolerance”) in food. This exemption does not apply to the actual pesticidal substance, which will continue to be fully evaluated by the Agency to ensure that it is safe for human health and the environment.

In a related action, EPA is inviting public comments over the next 30 days on three exemptions from today’s rules which were first proposed in 1994 but are not part of this rulemaking. The proposed exemptions are:

- PIPs derived through genetic engineering from plants that are able to naturally propagate;
- PIPs that act primarily by affecting the plant (such as causing the plant to have thicker wax cuticles); and
- PIPs based on viral coat proteins (substances that encapsulate and protect the genetic material of certain plant viruses).

EPA is also seeking public comments on the National Academy of Sciences report, published in April 2000, entitled “Genetically Modified Pest-Protected Plants: Science and Regulation,” as it relates to plant-incorporated protectants derived through genetic engineering. More information on all of these actions is available at: www.epa.gov/pesticides/biopesticides .

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